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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/901,181

07/09/2001

J. Lawrence Burg

97,195-P

6516

20306

7590

10/13/2005

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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/901,181

Applicant(s)

BURG ET AL.

3

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

This Office Action is responsive to the Amendment received on August 1, 2005.

#### ***Change in Examiner of record***

The Examiner of record has been changed. All further correspondence regarding this application should be directed to Examiner Young J. Kim whose Group Art Unit is 1637.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claim 21 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on March 29, 2005 is withdrawn in view of the Amendment received on August 1, 2005.

#### ***Rejection – New Grounds***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 24, and 31, 33, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite for reciting the phrase, "said reaction mixture from said first reaction vessel," because claim 10 recites (parent claim) that, "a nucleic acid amplification mixture" is formed and transferred to a second reaction vessel. While the phrase, "reaction mixture" does appear in claim 10, this mixture is not the product that is being transferred to the second reaction vessel. Clarification is requested.

Claim 15 recites the limitation, "said nucleic acid polymerization enzyme." There is insufficient antecedent basis for this limitation.

Claim 15 recites the terms, “said nucleic acid polymerization enzyme,” and “said nucleic acid amplification enzyme.” It is unclear whether the two enzymes are the same enzymes or they are different enzymes. As the polymerization enzyme does not find antecedent basis in its parent claim, it is assumed that the two terms are the same – nucleic acid amplification enzyme.

Claim 15 is indefinite for reciting the phrase, “said apparatus transfers said nucleic acid enzyme *contained in said second reaction vessel* to said first reaction vessel,” because the parent claim recites that the nucleic acid amplification enzyme is added in the first reaction vessel to form a nucleic acid amplification mixture and then transferred to the second reaction vessel (*see* claim 10, step d). Hence, there is no antecedent basis for a nucleic acid enzyme being present in a second reaction vessel to transfer from.

Claim 24 refers to “said enzyme.” Its parent claim (claim 16) recites two enzymes. It is unclear to which enzyme claim 24 is referring to.

Claim 31 is indefinite for reciting the phrase, “said automated apparatus *transfers said reaction mixture to said second reaction chamber*,” because the parent claim (claim 27) recites that the amplification mixture (*see* step b) is transferred to a second reaction chamber. While claim 27 does recite the term, “reaction mixture,” this mixture is further mixed with a nucleic acid amplification enzyme, resulting in an “amplification mixture” then transferred to the second reaction vessel.

Claim 34 is indefinite by way of its dependency on claim 31.

Claim 33 recites the phrase, “said reaction vessel.” There are two reaction vessels in its parent claim (claim 27). It remains unclear which of the two vessels the phrase is referring to.

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***Double Patenting – Maintained***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 10, 14-16, and 21-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 made in the Office Action mailed on March 29, 2005 is maintained for the reasons of record.

The rejection of claims 11-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 in view of Backus et al. (U.S. Patent No. 6,280,930), made in the Office Action mailed on March 29, 2005 is maintained for the reasons of record.

The rejection of claims 11 and 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 in view of Backus et al. (U.S. Patent No. 6,280,930) and Harris et al. (U.S. Patent No. 5,849,544) made in the Office Action mailed on March 29, 2005 is maintained for the reasons of record.

The rejection of claims 19-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 in view of

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Collins et al. (U.S. Patent No. 6,268,128) made in the Office Action mailed on March 29, 2005 is maintained for the reasons of record.

With regard to the above obviousness-type double patenting rejections, Applicants have not made any arguments to the contrary. In addition, Applicants stated that a terminal disclaimer will be filed (page 6, bottom paragraph, Response).

As a properly filed terminal disclaimer has not been made of record, the rejection is maintained.

*New Grounds – Necessitated by Amendment*

Claims 27-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,300,068. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 1 of U.S. Patent No. 6,300,068 (herein the '068 patent) recites all of the method steps of instant claim 27.

With regard to instant claim 28, claim 6 of the '068 patent recites that an internal control is used.

With regard to instant claim 29, claim 1, step (j) of the '068 patent recites that a detection is achieved.

With regard to instant claim 30, claim 1, step a) of the '068 patent recites that a sample is combined with a reaction buffer, a mixture of free nucleotide, a first and second specific nucleic acid primers.

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With regard to instant claim 31, claim 1, step d) of the '068 patent recites that the reaction mixture is transferred to a second reaction chamber.

With regard to instant claim 32, claim 1, step j) of the '068 patent recites that the automated apparatus displays a value for the detected label probe and optionally records the value for the signal.

With regard to instant claim 33, claim 5 of the '068 patent recites that the nucleic acid amplification enzyme is placed in a second reaction vessel in a lyophilized pellet.

With regard to claim 34, claim 4 of the '068 patent recites that the enzyme is placed in the first reaction chamber (which comprises the reaction mixture, thus brought into contact) as well as claim 1, step e) of the '068 patent which recites that the reaction mixture is brought into contact with nucleic acid polymerization enzyme.

With regard to claims 35 and 36, claim 1, step e) of the '068 patent recites that the two reaction chambers are fluidically connected, wherein the passage is explicitly disclosed as being regulated via a valve such as a thimble valve (column 13, lines 9-12).

The claims are obvious over the claims of the '068 patent therefore.

### ***Conclusion***

No claims are allowed.

### ***Inquiries***

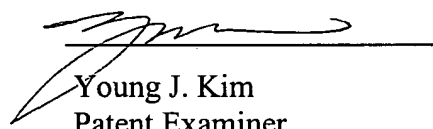
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The

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Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

  
Young J. Kim  
Patent Examiner  
Art Unit 1637  
10/12/2005

**YOUNG J. KIM**  
**PATENT EXAMINER**

yjk